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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,120	04/07/2004	Stephen J. Brown	/ 014030.0161PTUS	8225

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HEALTH HERO NETWORK, INC.
2000 SEAPORT BLVD.
SUITE 400
REDWOOD CITY, CA 94063

EXAMINER

MILLER, MARINA I

ART UNIT PAPER NUMBER

1631

DATE MAILED: 09/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/821,120	BROWN ET AL.	
	Examiner	Art Unit	
	Marina Miller	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 9/24/04 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>9/24/04; 1/4/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' submissions filed on 4/7/2004, 9/24/2004, and 1/4/2005 are acknowledged.

Claim 1 is pending. Claim 1 presently is under examination.

The following rejections and/or objections are applied.

Information Disclosure Statement

The information disclosure statements ("IDS") filed 9/24/2004 and 1/4/2005 have been considered in part. The IDS filed 9/24/2004 comprises references which are not properly cited; some references are missing a date of publication and several are missing a place of publication (*e.g.*, journal title or publisher's name and city), an author, and page numbers. The IDS filed 1/4/2005 also comprises references, which are not properly cited; many references are missing a date of publication and several are missing a place of publication (*e.g.*, journal title or publisher's name and city), an author, and page numbers. *See* MPEP 707.05(a)-(f) and 37 CFR 1.97 and 1.98 for IDS requirements. References, which are improperly cited, have not been considered and are crossed out. The examiner's initials indicate references that have been considered.

It is noted that many references listed on the IDS filed 1/4/2005 are duplicates of the references listed on the IDS filed 9/24/2004. These references have been crossed out to avoid duplication upon printing.

The information disclosure statement filed 1/4/2005 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. Specifically, Japanese applications cited on the IDS and EP-0653718 are not accompanied by an explanation

of the relevance. It has been placed in the application file, but the information referred to therein has not been considered.

The information disclosure statement filed 1/4/2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. Specifically, a copy of EP-08131551 has not been filed with the USPTO. It has been placed in the application file, but the information referred to therein has not been considered.

Considered references and references cited on Form 892 need not be re-cited on a new IDS. However, if applicants desire consideration of all references, the nonconsidered (crossed out) references must be cited in proper format on a newly submitted IDS. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Drawings

The drawings are objected to because Fig. 24 is a duplicate of Fig. 1. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as

“amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the examiner does not accept the changes, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 1 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 1 is drawn to a system for processing medical knowledge comprising a database, a rendering engine, and a feedback engine. It is not obvious that the claim is directed to an apparatus (as claimed) because it is not known what structural components (hardware, software) are specifically required by the claims; therefore, the system is not interpreted to be a device. Specifically, a database may be, for example, data stored in a computer memory. A rendering engine and a feedback engine are not necessarily a processor or a computer, but may be a program. Thus, the claims read on a computer program. Computer programs, *per se*, are not

statutory. A computer program is not a physical “thing.” It is neither a computer component nor a statutory process, as it is not “act” being performed. Such claimed computer programs do not define any structural and functional interrelationships between the computer program and other claimed elements of a computer, which permit the computer program’s functionality to be realized. *See Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility*. 1300 O.G. 4, on 22 November 2005 (published at the USPTO web site <http://www.uspto.gov/web/patents'patog/week47/OG/TOC.htm>).

Lack of Utility

Claim 1 is rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

Claim 1 is directed to a system comprising a database of medical knowledge, a rendering engine to convert the knowledge to a suitable format, and a feedback engine to receive feedback from a patient to the database. There is no well-established utility for the system. It is also not clear what one would use the system for and what “practical” result is produced by the system. The “usefulness” of the system is not apparent.

The specification discloses on page 3 that e-health care management tools may be used for identifying patient characteristics that correlate to disease progression, enables providers and patients to predict, prevent, and manage diseases. However, the alleged utility is not commensurate with the claimed invention because the claim is not limited to correlating patient characteristics and disease progression and to predicting, preventing, and managing diseases. A system for processing medical knowledge may have a “substantial” utility, if one knows the parameters and/or purpose of the processing. In the instant case, further research would require

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to confirm the use of general medical knowledge and “a general feedback” received from a patient. Therefore, converting medical knowledge and receiving feedback from a patient would require or constitute carrying out further research to identify or reasonably confirm a “real world” context of use.

Further, the instant invention does not have specific utility. Specifically, a system for processing medical knowledge is generally useful, but one of skill in the art would have to know something particular, such as a stated correlation between medical knowledge, patient characteristics, disease, and/or feedback received from the patient. Instead, the claim merely recites a system for processing general “medical knowledge” and receiving a general “feedback” from a patient,” which IS generic. There is no connection between medical knowledge and disease AND a feedback received from a patient, *i.e.*, whether the feedback is actually associated with a disease. A utility does not need to be recited in the claim; however, one must be able to use the CLAIMED invention for the asserted utility without further experimentation.

Although it may be credible that the claimed invention has the above mentioned utilities, the lack of a specific and substantial utility, as explained above, sufficiently supports lack of patentable utility under 35 U.S.C. 101.

Enablement under 35 U.S.C. § 112, first paragraph

Claim 1 is also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 102

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Schneider, US 4,465,044.

Schneider discloses a method and a computer system for determining fertility status (abstract). Schneider discloses storing information about the female user's past history related to, for example, a menstrual cycle activity (*i.e.*, a database of medical knowledge) and ontology specifying use of the knowledge for specific conditions (gynecology, fertility, menstrual cycle, basal body temperature, cycle length, *etc.*) (col. 2-4; and table in col. 4-5). Schneider discloses a rendering engine for converting medical knowledge (stored female patient information) to a suitable format for a presentation to a patient (a computer processor stores data related to a menstrual cycle and displays information to a user on a user's computer) (col. 3, line 36-col. 4, line 17; fig. 2 and 6; claim 1). Schneider discloses "a feedback" from a patient and providing the current status to the database (claim 1; col. 2, line 53 through col. 3, line 18; col. 19, line 67 to col. 21, line 56). Thus, Schneider anticipates claim 1.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Dunning, US 4,296,756.

Dunning discloses testing a remote pulmonary function (abstract and fig. 1 and 6). Dunning discloses a computer memory storing patient information (a database of medical knowledge) (col. 11, line 28 through col. 12, line 32; claims 1, 4, and 6; fig. 1 and 6). Dunning discloses ontology specifying use of medical knowledge for specific conditions (pulmonary function and air flow volume). Dunning discloses a rendering engine for converting medical knowledge (stored patient information about flow volume and medical diagnosis) to a suitable format for a presentation to a patient (a computer processor stores data related to an air flow volume, processes data, and displays information to a user on a user's computer) (claims 1-3; col. 8, lines 14-21; fig. 1 and 6). Dunning discloses "a feedback from a patient" to a database (col. 3, lines 25-27; col. 7, lines 36-39; col. 11, lines 18-24). Thus, Dunning anticipates claim 1.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Iliff, US 6,270,456.

Iliff discloses a method and a system for providing computerized, knowledge-based medical diagnostic advice over a network (abstract). Iliff discloses a database of medical knowledge (fig. 2-3) and ontology specifying use of medical knowledge for specific conditions (fig. 3-4, 6, 10-11; claims 1-5; col. 3-4). Iliff discloses a rendering engine for converting medical knowledge to a suitable format for a presentation to a patient (a user's computer is connected to a database, wherein the user may browse the database) (col. 4, lines 13 through col. 4, line 51). Iliff discloses "a feedback from a patient" to a database (a "dialog" between a patient and a computer according to a medical diagnosis script that allows generating a diagnosis for a patient) (col. 6, line 21-31; col. 13, lines 40-50; col. 21, lines 2-60). Thus, Iliff anticipates claim 1.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Brown, US 6,161,095.

Brown discloses a method and a system for monitoring compliance with a treatment regimen (abstract, fig. 1). Brown discloses a database of medical knowledge (a database of treatment regimens and compliance; fig. 1-2, col. 4, lines 7-11; col. 6, lines 63-65). Brown discloses ontology specifying use of medical knowledge for specific conditions (symptomology, specific drugs, side effects, *etc.*; col. 2-3, bridging paragraph). Brown discloses a rendering engine for converting medical knowledge to a suitable format for a presentation to a patient (sending information from a server to a patient's device having a presentation element; col. 4, lines 37-41; fig. 1-2). Brown discloses "a feedback from a patient" to a database (a patient's device comprises a patient feedback input element, which transfers a feedback to a database stored on a server; col. 4, lines 40-41; fig. 1-3). Thus, Brown anticipates claim 1.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Miller whose telephone number is (571)272-6101. The examiner can normally be reached on 8-6, M-Thu.

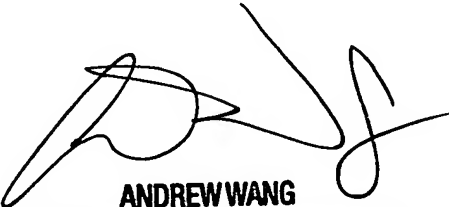
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, Ph. D. can be reached on (571)272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Marina Miller
Examiner
Art Unit 1631

MM



ANDREW WANG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600